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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,456	11/02/2001	Timothy R. Owens	5618P2971	5019
8791	7590	03/23/2005	EXAMINER	
BLAKELY SOKOLOFF TAYLOR & ZAFMAN 12400 WILSHIRE BOULEVARD SEVENTH FLOOR LOS ANGELES, CA 90025-1030			ROY, BAISAKHI	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/008,456	OWENS ET AL.	
	Examiner	Art Unit	
	Baisakhi Roy	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/22/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al. (5817017). Young et al. disclose an apparatus comprising a medical device such as a catheter with a plurality of target markers, adapted to be inserted in an anatomy and where a MRI system operating at 1.5 Tesla will detect the device with enhanced visibility and not disregard the medical device as noise (abstract, col. 3 lines 61-67, col. 4 lines 1-14, col. 6 lines 12-26, col. 7 lines 21-24, col. 14 lines 11-14). Young et al. teach said flexible and expandable medical device to comprise a polymer material and markers to be composed of paramagnetic material (col. 6 lines 34-65, col. 12 lines 37-67, col. 13 lines 1-20). Young et al. teach determining the location of the device in relation to the anatomy (col. 3 lines 48-61).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 4-10, 13-24, 27-35, 38-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Gillies et al. (6272370).

Regarding claims 1, 4, 7-9, 13, 16, 19-22, 23, 27, 33, 34, 38, and 44, Gillies et al. teach an apparatus and method of inserting a medical device such as a catheter with a plurality of target markers into an anatomy, scanning a MRI image of the anatomy with said MRI processor having the ability to detect low-level signals, processing the scanned image, determining a location and orientation of the medical device in relation to the anatomy, and displaying a precise image of the device within the anatomy where the device is not depicted as noise for MRI systems (col. 6 lines 27-49, col. 8 lines 16-31, col. 11 lines 5-13, col. 14 lines 41-60, col. 27 lines 7-40).

Regarding claims 10, 24, 32, 35 and 43, Gillies et al. teach said method and apparatus pre-scanning the medical device before inserting in an anatomy, storing and transmitting a plurality of image data to the processor, and withdrawing the device from the anatomy at an adjusted pace (col. 11 lines 5-18, col. 12 lines 37-55, col. 28 lines 55-67).

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Regarding claims 5, 6, 14, 15, 28, 29, 39, and 40, Gillies et al. teach said medical device to be expandable and composed of polymer material (col. 25 lines 15-25, col. 28 lines 52-55).

Regarding claims 17, 18, 30, 31, 41, and 42, Gillies et al. teach superimposing an image of the medical device over the anatomy by replacing a plurality of pixels of an anatomy with a plurality of pixels of the medical device (col. 11 lines 5-13 lines 31-64).

Regarding claims 45-49, Gillies et al. teach a MRI system comprising a scanner, a processor, a control unit, and a display with the ability to detect low-level signals from a medical device with a plurality of target markers which is inserted into an anatomy, where the device is not depicted as noise for MRI systems, and the location and orientation of said device is determined prior to insertion into an anatomy (col. 6 lines 27-49, col. 8 lines 16-31, col. 11 lines 5-13, col. 14 lines 41-60, col. 27 lines 7-40).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2, 3, 11, 12, 25, 26, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. in view of Young et al.

Regarding claims 2, 11, 25, and 36, Gillies et al. teach the use of a plurality of target markers as set forth above, but do not explicitly teach said markers to be one of ferromagnetic and paramagnetic material. In the same field of endeavor, Young et al.

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teach said medical device to be composed of paramagnetic material (col. 6 lines 34-65, col. 12 lines 37-67, col. 13 lines 1-20). It would have therefore been obvious to one of ordinary skill in the art to use the marker material composition teaching by Gillies et al. to modify the teaching by Young et al. for the purpose of using a paramagnetic material to generate images with enhanced visibility of the medical device.

Regarding claims 3, 12, 26, and 37, Gillies et al. do not explicitly teach the magnetic field strength of the MRI system. It is well known in the art that diagnostic MRI system employ magnets with operating field strengths in the range of 0.02 T to 1.5 T. In the same field of endeavor, Young et al. teach the use of a MRI system operating at 1.5 Tesla (col. 14 lines 10-15). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Young et al. to modify the teaching by Gillies et al. for the purpose of applying an appropriate magnetic field strength.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for relevant references of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. R.

BR


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